DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 2 1986

Re: Orthoclone OKT*3
Docket No. 86E-0357

Mr. Charles E. Van Horn, Esq.
Director, Patent Examining Group 120
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the application for patent extension for U.S. Patent No. 4,361,549, filed by Ortho Pharmaceutical Corp. under the patent extension provisions of 35 U.S.C. 156 et seq. The human drug product claimed by the patent is Orthoclone OKT*3 (muromonab-CD3), Product License Application (PLA) numbers 84-149 and 84-150 and U.S. License number 996.

A review of the Food and Drug Administration's official records indicates that Orthoclone OKT*3, the product identified in the patent extension application, was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that the product represents the first permitted commercial marketing or use of the active ingredient, muromonab-CD3. The Product License was approved on June 19, 1986 which makes the submission of the patent extension application on August 12, 1986 timely within 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A), we will then determine the applicable regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

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Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Leonard P. Prusak
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